Effective Date: April 17, 1997

COORDINATED ISSUE
PHARMACEUTICAL INDUSTRY
MEDICAID REBATES

ISSUE

Whether a pharmaceutical manufacturer may accrue its liability for Medicaid rebates payable pursuant to a contract with a State prior to actual payment of the rebate, using an estimate of the amount of its rebate liability?

CONCLUSION

A pharmaceutical manufacturer may not accrue its liability for Medicaid rebates until the taxable year in which it pays the rebate.

THE MEDICAID REBATE PROGRAM

The Omnibus Budget Reconciliation Act of 1990 established the Medicaid Drug Rebate program. Pub. L No. 101-508, § 4401. The rebate program applies to drugs dispensed on or after January 1, 1991. The primary goals of the rebate program are to enable Medicaid to achieve savings in drug expenditures and to increase Medicaid beneficiaries' access to drugs. Implementation of the program has been accomplished through a complex partnership among the Department of Health and Human Services (HHS), State Medicaid agencies and pharmaceutical manufacturers. HHS delegated the authority to operate this program to the Health Care Financing Administration (HCFA).

Section 1396r-8 of Title 42 of the United States Code sets forth the operational provisions of the rebate program. Section 1396r-8(a) provides that in order for payment to be available under the program for covered outpatient drugs, the manufacturer must enter into a rebate agreement with the Secretary, who is acting on behalf of the States.

Section 1396r-8(b) provides the terms of the rebate agreement. In general, a rebate agreement requires the manufacturer to provide, to each State, a rebate each calendar quarter in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed under the plan during the calendar quarter. Each manufacturer must report to HCFA, not later than 30 days after the last day of each

quarter, on the average manufacturer price[1] and the manufacturer's best price[2] for covered outpatient drugs for the quarter. HCFA uses this pricing information to compute the unit rebate amount (URA).

Medicaid utilization data is information compiled by each State on the total number of units of each dosage form and strength of the manufacturer's covered outpatient drugs reimbursed during a quarter. Medicaid utilization data is based on claims paid by the States during a quarter and not on drugs dispensed during a quarter. HCFA provides the URA to the States within 45 days after the end of each quarter. The URA times the number of units utilized equals the amount of rebate due from the manufacturer for a given drug product. A State may calculate its anticipated rebate, but it is the primary responsibility of the manufacturer to correctly calculate the rebate amount.

Each State agency submits a utilization report to each manufacturer not later than 60 days after the end of each calendar quarter. Section 1396r-8(b)(2)(A). The utilization report contains information on the total number of dosage units of each covered outpatient drug paid under the plan and the unit rebate amount due for that quarter. The rebate must be paid by the manufacturer not later than 30 days after the date of receipt of the utilization report from the State agency responsible for the plan. Section 1396r-8(b)(1)(A).

States have encountered problems reconciling rebate amounts due with manufacturers. Reconciliation problems can occur for several reasons, including: 1) claims billing problems with pharmacies that are not detected by system edits, including differing use of unit types by pharmacies; (2) manufacturers' attempts to verify Medicaid utilization data using non-Medicaid specific proprietary data sources; and (3) drug coding errors made as prescriptions are filled. See Impact of the Medicaid Drug Rebate Program, Extramural Research Report of the Health Care Financing Administration, U.S. Department of Health and Human Services (August, 1995), p.16. Because of these problems in reconciliation, portions of claims filed by the States with manufacturers are sometimes disputed. Under the rebate agreement, dispute resolution provisions are

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1The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. § 1396r-8(k)(1).

2The term "best price" means the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity. The best price is inclusive of cash discounts, free goods, volume discounts, and other rebates. It is determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package and does not take into account prices that are merely nominal. § 1396r-8(c)(2)(B).

provided in the event of a disagreement between the participating manufacturer and the States. If the dispute cannot be informally resolved, the rebate agreement mandates that the State offer the manufacturer a formal hearing to resolve claim disputes.

LAW AND ANALYSIS

Section 162 provides a deduction for all ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business. Section 461 governs when a taxpayer may deduct an expense deductible under section 162. Under section 461(a), the amount of any allowable deduction or credit is taken in the taxable year which is the proper taxable year under the method of accounting which is used in computing the taxpayer's taxable income.

Under an accrual method of accounting, three requirements must be met in order to accrue a liability for tax purposes in a taxable year: (I) all events have occurred which fix the fact of the liability, (ii) the amount of the liability can be determined with reasonable accuracy, and (iii) economic performance has occurred with respect to the liability. Treas. Reg. § 1.461-1(a)(2)(I). Moreover, while no liability can be taken into account before economic performance and all of the events that fix the liability have occurred, the fact that the exact amount of the liability cannot be determined does not prevent a taxpayer from taking into account that portion of the amount of the liability which can be computed with reasonable accuracy within the taxable year. Treas. Reg. § 1.461-1(a)(2)(ii).

The All Events Test and the Terms of the Contract

A manufacturer's liability for Medicaid rebates is not fixed until the year the claims for reimbursement are filed by the States. Where a taxpayer's obligation to pay expenses is based on a contract, here the rebate agreement, the terms of the contract are relevant in determining what events fix the taxpayer's right to income and its liabilities. See, e.g., United States v. General Dynamics, 481 U.S. 239 (1987); Lucas v. North Texas Lumber Co., 281 U.S. 11 (1930); Decision, Inc. v. Commissioner, 47 T.C. 58 (1966); Estate of G.A.E. Kohler v. Commissioner, 37 B.T.A. 1019 (1938).

The two leading cases on when a liability is fixed are United States v. Hughes Properties, 476 U.S. 593 (1986) and United States v. General Dynamics, supra. In Hughes Properties, an accrual method casino operator deducted as a business expense the amount guaranteed for payment on progressive slot machines. A state regulation prohibited reducing the payoff without paying the jackpot. The Court held that the regulatory provision fixed the taxpayer's liability for the progressive jackpot.

The Court reasoned that the event creating liability was the last play of each progressive machine before the end of the fiscal year since that play fixed the jackpot amount irrevocably. The Court also indicated that the possibility that a jackpot might not be paid due to subsequent events did not preclude the deduction.

In General Dynamics, the Court held that the taxpayer, which was a self-insurer of its employee medical expenses, could not deduct reserve accounts reflecting liabilities for medical care provided during the year to employees who had not yet filed claims for reimbursement during that year. **The Court held that the last event necessary to fix the liability was not the receipt of medical care by covered individuals, but the filing of properly documented claim forms.** Filing of a claim was a condition precedent to the taxpayer's liability. Thus, the taxpayer could not deduct an estimate of its obligation to pay for medical care obtained by its employees or their qualified dependents during the final quarter of the year when the claims had not been filed by year end. The Court also stated that a taxpayer cannot deduct an estimate of an anticipated expense, no matter how statistically certain, if it is based on events that have not occurred by the close of the tax year. The Court noted that the taxpayer's ability to make a reasonable estimate of its liability based on actuarial data did not alone justify a deduction. The Court clarified Hughes Properties by stating that the failure to file a claim form was not the type of "extremely remote and speculative possibility" that renders an otherwise fixed liability contingent. General Dynamics, 481 U.S. at 243.

Fixing Liability -- the State's Utilization Report

Under the terms of the rebate agreement, at the close of each quarter, each manufacturer must submit its average manufacturer price and best manufacturer price to HCFA. HCFA reviews this data and sends it to the States. The States create a utilization report. The utilization report is based on claims paid by each State's Medicaid Agency during a calendar quarter. The utilization report is not based on drugs dispensed during a calendar quarter. The utilization report is information on the total number of units of each dosage form and strength of the manufacturer's covered outpatient drugs reimbursed during a quarter. Upon receipt of the State utilization report, the manufacturer is obligated, under the terms of the contract, to pay the rebate amount within 30 days.

A State may obtain payment of the rebate only by submitting a utilization report to the manufacturer. The manufacturer is obligated to make rebate payments within 30 days after receiving the utilization report. The filing of the report is not a mere technicality. Amounts for which a State never submits a utilization report will never be paid by the manufacturer. Accordingly, the last event fixing the liability of the manufacturer to pay the rebate is the receipt of the utilization report submitted by the State.

Taxpayers rely on Hughes Properties for support to accelerate the deduction of the rebate. Taxpayers argue that, once a covered drug is dispensed to a Medicaid beneficiary, the liability is fixed because it is legally obligated to pay the rebate. Dispensing the covered drug to a Medicaid beneficiary starts a chain of events that are all required to be performed under the Medicaid law. The pharmacist is obligated to file a reimbursement claim with the State, the State is obligated to pay the pharmacist, the drug manufacturer is required to provide HCFA with pricing information, the State is obligated to submit a utilization report, and the drug manufacturer is obligated to pay a rebate to the State. Further, taxpayers argue that the possibility that these events would not occur is extremely remote and speculative; that is, the filing of the report is ministerial.

This argument fails to account for several possibilities. For example, at the beginning of the chain of events, the pharmacist may not submit the claim for reimbursement or the State may deny the claim because its requirements have not been fulfilled or there may not be a pricing difference. If these events occurred, the manufacturer may have no liability for a rebate, or it may be deferred. Furthermore, even upon receipt of the utilization report, reconciliation problems may occur, resulting in payment disputes. Dispute resolution provisions are included in the rebate agreement, and the occurrence of disputes is not uncommon. Thus, although payment has been made by the State, the manufacturer's liability for the rebate may be less than claimed by the State, or it may be deferred.

Accordingly, even if a manufacturer is able to make a reasonable estimate of its rebate liability for those months in a taxable year during which it has dispensed drugs eligible for Medicaid reimbursement, but for which it has not yet received a utilization report from the State, a manufacturer may not accrue a deduction. The fact of liability is not fixed, and the all events test is not met, until the manufacturer receives the State utilization report.

Economic Performance -- Payment Obligation -- Accrual When Paid

Section 461(h)(1) provides, generally, that in determining whether an amount has been incurred during any taxable year, the all events test is not met any earlier than when economic performance with respect to such item occurs. Economic performance requirements for those liabilities not specifically dealt with in section 461(h) are determined under the regulations.

In the case of payment liabilities, such as rebates, economic performance occurs when and to the extent that payment is made to the person to which the liability is owed.

Treas. Reg. § 1.461-4(g)(1).[3] If the liability of a taxpayer is to pay a rebate, refund or similar payment to another person, economic performance occurs as payment is made to the person to which the liability is owed. Treas. Reg. § 1.461-4(g)(3). Accordingly, taxpayers cannot deduct the rebates in any taxable year prior to the taxable year in which they actually pay the rebate, unless they qualify for the recurring item exception, discussed below.

The Recurring Item Exception -- Accrual Prior to Payment

The economic performance rules contain an exception for accrual method taxpayers with recurring items. Section 461(h)(3). Under this exception, a liability is treated as incurred during a taxable year, notwithstanding section 461(h)(1), if:

> (I) as of the end of the taxable year, the taxpayer has met the all events test (without regard to economic performance);
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> (ii) economic performance with respect to the liability occurs on or before the earlier of (A) the date the taxpayer files a (including extensions) timely return; or (B) the 15th day of the 9th calendar month after the close of that taxable year;
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> (iii) the liability is recurring in nature; and
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> (iv) either (A) the amount of the liability is not material; or (B) the accrual of the liability for that taxable year results in a better matching of the liability with the income to which it relates than would result from accruing the liability for the taxable year in which economic performance occurs.

For this purpose, the all events test is met with respect to any item if all events have occurred which determine the fact of liability and the amount of such liability can be determined with reasonable accuracy. Section 461(h)(4). The liability for Medicaid rebates is a recurring liability. Also, in the case of rebates, the matching requirement is deemed satisfied. Treas. Reg. § 1.461-5(b)(5)(ii). Accordingly, if all the events are met

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3The final regulations for payment liabilities are effective for taxable years beginning after December 31, 1991.

prior to the end of the tax year, the recurring item may be available to manufacturers. Because the liability for Medicaid rebates is not fixed until the year the State utilization report is received by the manufacturers, the recurring item exception is not available to most manufacturers,[4] and will not be available to any manufacturer whose taxable year is the calendar year.

Accordingly, most manufacturers do not meet the requirements for the recurring item exception for the unpaid portion of the Medicaid rebates attributable to a taxable year. Therefore, economic performance does not occur until the taxable year the rebates are paid.[5] Because the State agencies send Medicaid rebate utilization reports to the manufacturers on a quarterly basis, the taxpayer will be able to deduct a portion (usually three quarters) of its Medicaid rebates attributable to a calendar year. However, that portion of the Medicaid rebate liability which is paid by the taxpayer in the following taxable year may be deducted only in the year of payment.

Change in Method of Accounting

For those manufacturers who do not qualify for the recurring item exception, a change from deducting the rebate liability prior to the year of payment to deducting the liability in the year of payment is a change in method of accounting to which the provisions of sections 446 and 481 apply. The net adjustment required under section 481(a) is computed as of the beginning of the year of the change in method of accounting.

4Some fiscal year end manufacturers may receive the utilization reports prior to fiscal year end and thus may be eligible for the recurring item exception.

5Since the manufacturer does not pay the State until it receives the utilization report, the fixing of the fact of liability precedes payment of the rebate. Therefore, the all events test is met prior to payment of the rebate and does not delay the manufacturer's accrual of the rebate in the year in which the rebate is paid.